REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-148 are pending in this case. Claims 34-148 were withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 1-33 have been rejected.

By this amendment, claim 1 has been amended.

Attached herewith is a marked up version of the changes made to the claims by the current amendment.

Claim Rejections – 35 USC § 102 - LePivert

The examiner has rejected claims 1-3 and 5-15 under 35 U.S.C. § 102(e) as being anticipated by LePivert in U.S. Pat. 6,235,018. The Examine's rejections are respectfully traversed. Claim 1 has now been amended.

It is the Applicant's opinion that considerations presented below justify the view that the claimed invention is both structurally and functionally distinct from that described by LePivert. However, to further remove any ambiguity in this regard, independent claim 1 has been amended to more clearly distinguish between the claimed invention and the system described by LePivert.

The examiner states that LePivert discloses a planning system (fig. 5) for planning a cryosurgical ablation procedure, comprising: a first imaging modality (100) for creating digitized (column 6, line 62) preparatory images of an intervention site (column3, lines 41-45); a three-dimensional modeler (104) for creating a three dimensional model of the intervention site based on the digitized preparatory images, and a simulator (column3, lines 38-40) for simulating a cryosurgical intervention, which comprises an interface (150) useable by an operator for specifying loci for insertion of cryoprobes (106) and operational parameters (column 8, lines 27-31) for operation of cryoprobes for cryoablating tissues, and a displayer (108) for displaying in a common virtual space an integrated image comprising a display (column 8, lines 13-14) of the three dimensional model of the intervention site and a virtual display (anatomic image, column 8, line 15) of cryoprobes inserted at the loci. In this context the Examiner also refers in particular to LePivert's text (at column 7, lines 7-10).

The preponderance of the structures and funcitons described by LePivert are of course not directed to a planning system at all, but rather to a method and system for real-time monitoring of the progress of an ice ball produced by a cryoprobe during a surgical procedure. That is, whereas the claimed invention addresses a system for simulating an intervention, useable for planning, for example for evaluating possible surgical strategies in advance of undertaking a surgical procedure, the primary thrust and the preponderance of LePivert's description has to do with methods and systems for measuring the size of the zone of complete tissue destruction within the larger zone of frozen tissue, *during a surgical intervention*, based on measurements of electrical impedence. The few specific references by LePivert to simulation and prediction functions of his invention will be discussed in detail below.

(1) planning vs. real time

With reference to LePivert's Figure 5, one note's that althougth LePivert does present an imaging modality suitable for creating digitized preparatory images of an intervention site, one finds no reference to a three-dimensional modeler for creating a three-dimensional model of the intervention site based on the digitized preparatory images. Element 104 in LePivert's Figure 5 is a computer. Specific references to the functionality of computer 104 refer to its use "to process the impedance signals....to calculate the dimensions of the ice ball produced around the tip of a cryoprobe106." (column 6, lines 56-58, see also column 8, lines 8-12), and to produce on a display 108 an image of a eutectic zone, sized in response to the impedance data received (see column 7, lines 1-10 and column 8 lines 12-14). Note that the calculations here described for computer 104 involve real-time interpretation of impedance data received in real time during a surgical intervention, and as such are not intrinsically involved in any planning role. Note further that no mention is made of three-dimensional modeling during this process. The only image handling procedures mentioned appear to be registration of real-time calculated images with previously obtained "anatomic image" (column 7, lines 2-10). Moreover, the cited anatomic images provided as an example are specifically two-dimensional images: "Such image data may be reproduced, for example, by an X-ray CT, ultrasonic or MR imaging system (not shown in the drawings) that delivers fully reconstruced 2D images at a desired frame rate." (column 6, lines 63-67). Thus, the text indicates manipulation of 2D images. Three-dimensional modeling, an element of claim 1, is not at all mentioned by LePivert.

(2) 2D vs. 3D

Further with reference to LePivert's Figure 5, one notes that whereas LePivert contemplates a displayer (108) for displaying in a common virtual space an integrated image, the nature and content of said display is wholly different from that contemplated by the claimed invention. The image displayed in a common virtual space, according to LePivert, combines anatomic images gleaned from imaging modalities (either prior to, or during, a surgical procedure), combined with computer generated images of freezing zones calculated on the basis of real-time electrical impedance data gleaned from the electrical impedence measurements taken during cryoablation, using measuring and calculating apparatus and methods presented by LePivert. Thus, the combined image provided by LePivert combines anatomical images from standard imaging modalities combined with an image generated from real-time impedence data gleaned during the process of a cryoablation procedure. In short, LePivert's system combines two-dimensional anatomical images with algorithmically generated image(s) of freezing zones, as calculated from real-time electronic data during cryoablation.

In contrast, claim 1 comprises a simulator able to display a three-dimensional image based on a three-dimensional model of an intervention site, which three-dimensional model is based on (but not identical to) two-dimensional images from standard imaging modalities, gleaned prior to an intervention. A three-dimensional view of this three-dimensional model is presented, combined with images of *virtual* (i.e., non-actual) *simulated* cryoprobes, virtually inserted at loci specified, with respect to that three-dimensional model, by an operator. Thus, LePivert's invention combines anatomical images with real-time images showing results of an actual intervention in progress, whereas claim 1 describes a system utilizing two-dimensional anatomical images to present a three-dimensional model, and then combining that three-dimensional model with virtually presented results of a simulated, hypothetical, intervention.

To further clarify the distinction between the claimed invention and the teachings of LePivert, claim 1 has now been amended. Claim 1, (c) (ii) now reads as follows:

> (ii) a displayer for displaying in a common virtual space an integrated image comprising a display of

said three-dimensional model of said intervention site and a virtual display of simulated cryoprobes inserted at said loci.

Thus, the word "simulated" has been added to claim one, to further emphasize that the cryoprobes displayed are simulated cryoprobes displayed at a locus selected by an operator, that locus being defined with respect to the three-dimensional model also displayed, together with the simulated cryoprobes, in a common virtual space, shown in a common display. This system is thus in sharp distinction to that described by LePivert, designed to display cryoprobes' actual positions during an actual intervention. This distinction is, of course, equally relevant to the various dependent claims, as will be discussed in detail below.

To avoid confusion, attention must be paid to occasional dissimilar uses of similar terms, in descriptions of the two systems. The instant application, for example, refers (on page 48, line 7 through page 49 line 16) to predicting and displaying a predicted zone of freezing, prediction being based on theoretical and/or historical empirical considerations, and being rendered with respect to a selected virtual positioning of one or more simulated cryoprobes with respect to a three-dimensional model of a target ablation site. In sharp contrast, LePivert describes a system which enables to "predict" (column 2, line 54) zones of eutectic tissue desctruction, that "prediction" being an estimate of a zone of freezing, which estimate is based on a mathemateical model applied to actual physical measurements taken during actual cryoablation.

References to non-real-time uses (e.g., for planning, for simulation, for teaching) of LiPivert's system appear to be limited to a single place in his disclosure, two sentences if his summary section. The first sentence is: "The invention may be used for the purpose of simulation of different operative conditions, in order to train and guide surgeons." (column 3, lines 39-41), followed by a second sentence: "The registered computerized images provided by the invention may be compared with the pre or per operative images of the lesion, and the information used to control the placement and operation of the cryoprobe." (column 3, lines 41-45).

On close inspection, the second quoted sentence does not appear to refer, however, to a non-surgical use of the system. Note that the "registered computerized

images provided by the invention" referred therein integrate "anatomical images" (present or pre-recorded) with real-time data gleaned during an actual intervention. Since such images depend on real-time data, such images, and the use of such images, cannot be considered a simulation tool nor a planning tool. Conesquently, neither such images nor their use can be considered prior art with respect to a planning tool useable in advance of (or in absence of, e.g. for training) a surgical intervention.

With respect to LePivert's statement that "The invention may be used for the purpose of simulation of different operative conditions, in order to train and guide surgeons." cited above, one notes that this sentence appears to be the only reference in LePivert's entire disclosure, relating to possible planning or teaching or simulation functionality. No enabling implementation details are anywhere given, and it is unclear what exactly is to be simulated, how such a simulation might be used for training, and how it is to be accomplished. In sharps contrast to the instant application, wherein several methods for calculating an effect of use of a cryoprobe at a specified temperature for a specified length of time are mentioned, LePivert shows only methods for estimating the ablative effect as a function of measurable values of electrical impedence in body tissues. Yet, measurable changes in electrical impedence in body tissues are observable only during actual cryoablation; no details nor even general description of procedures for simulating these are described by LePivert. Consequently, LePivert's system has no predictive functions not dependent on real-time measurement of changes in electrical impedence, consequently it is unclear how one might use LePivert's system to simulate different operative conditions, nor how one might use such a simulation to train surgeons. Thus, while LePivert's system might indeed provide information useful to *guide* surgeons during an actual ablation procedure, LePivert's system system fails to anticipate the preoperative planning system of claim 1 and the claims that dependend therefrom.

To further preclude possible mis-understanding, the Examiner's attention is respectfully drawn to the following statement of LePivert, from column 2, lines 53-55: "As a result, one can predict the area of tissue destruction, in both surface as well as in depth, around the cryoprobe." Since this sentence bears superficial similarity to references, from the instant application, to "predicting" effects of ablation procedures, one notes here that the quoted use of the word "prediction" does not in fact refer to prediction of the effect of a cryoablation operation as a function of such parameters as

temperature of a probe, time of cooling, etc. Rather, the prediction in question is of the size of the eutectic freezing zone as a function of "the electrical model and the measured complex impedence" (column 2, line 48). Consequently this "prediction", however useful, does not constitute a prediction operable based on operator input alone, e.g., based on actions of a student operating a simulated procedure, and which might therefore constitute a basis for use of LePivert's system as a planning or simulation tool. LePivert's system, as described, does not appear to have any predictive characteristics, in absence of an actual measured change in impedence of body tissues, which changes are measurable only during actual, not simulated, ablation procedures.

In view of the foregoing, it is submitted that LePivert fails to anticipate claim 1, particularly as now amended, which is now allowable, rendering claims 2-3 and 5-15, which directly or indirectly depend from claim 1, also allowable.

Not withstanding from the above, Applicant has dditional arguments relating to the independent claims, as follows:

Re: claim 2, with respect to the passage in column 3, lines 16-22, cited by the Examiner with reference to the recording of data, we submit that in the sentence "Each probe is equipped with electrical connections and sensor to record data necessary to construct and display....", the words "to record data" reference data collection devices for real-time data collection from sensors embedded in tissues. This is to be contrasted with the recording and memory features described in the instant application, in particular with reference to Figure 11, where reference is made to a device for recording user choices for simulated positions and operations of virtual cryoprobes.

Re: claim 3, the Examiner points out that that LePivert also discloses use of CT, MRI, and ultrasound imaging. Difference in the uses to which those images are put, however, have been discussed in detail above.

Re: claims 5-10, the Examiner states that LePivert discloses the ability to highlight selected regions within the 3D model. The Examiner cites in particular column 4, lines 54-57. Yet, LePivert does not in fact refer to a three-dimensional model. LePivert does refer abundantly to the ability of his system to highlight selected regions, showing that, under reported parameter conditions and under observed and measured impedence data, highlighting can then be used, by the system,

to show estimated freezing zones of various types, in real-time. In contradistinction, claims 5-10 refer to highlight of regions *by an operator*. Usefulness of such highlighting by an operator is discussed in the instant application, particularly with reference to Figure 11, where a highlighter 280 is described as being used, under control of an operator, for highlighting selected regions within a three-dimensional model, for use in planning and simulation.

Re: claims 11-15, the Examiner points out that LePivert in his Figure 1 discloses different zones relevant to operation of a cryoprobe, for example a zone of complete tissue destruction, a zone of partial tissue damage but not of total desctruction, etc. The Examiner states that the demarcation of zones by LePivert in his Figure 1 is equivalent to disclosing a predictor for predicting probe effects on tissue.

The Applicant agrees that LePivert does indeed describe a predictor for predicting probe effects on tissue. However, LePivert's predictor is a predictor of effects on tissue *as a function of observed changes in electrical impedence during a cryoablation procedure*. This, is in sharp contrast to the predictor described in claim 11, which describes the system of claim 1 further comprising a predictor for predicting an effect, on tissues of a patient, of operation of cryoprobes at the referenced loci *"according to said operational parameters"*, where the referenced operational parameters are defined in claim 1 as being operational parameters for operation of cryoprobes for cryoablating tissues, *specifiable by an operator*. In other words, whereas LePivert's predictor makes predictions based on physical data measured during an operation, the predictor specified in claim 11 makes predictions based on user-supplied positional information regarding simulated cryoprobe positions defined with respect to a three-dimensional model of an intervention site, and on user-supplied operational information regarding operating characteristics of, and selected uses of, those simulated cryoprobes. Thus, LePivert's predictor, which may be useful in an active surgical context, has no role in a cryosurgical planning system such as is described by claim 1 and by claims dependent thereon.

Claim Rejections – 35 USC § 103(a) – LePivert

The Examiner has rejected claims 4 and 16-22 under 35 USC § 103(a) as being unpatentable over LePivert. The Examiner's rejections are respectfully traveresed.

It is believed by the Applicant that the explanations and arguments given above with respect to claim 1, with reference to thc Examiner's USC § 102 rejections, serve also to overcome these 35 USC § 103(a) rejections.

With respect to particular references cited by the Examiner:

With respect to the reference cited by the Examiner from column 3, lines 43-45 of LiPivert, where the Examiner points out that the phrase "the information (from the computerized images) used to control the placement and operation of the cryoprobe" indicates that the images provide a *recommended* course of action for thc impending surgery, one notes that the sentence fragment cited is taken from a paragraph which presents uses to which the invention may be put. In particular, the full sentence from which the fragment is taken reads: "The registered computerized images provided by the invention may be compared with the pre or per operative images of the lesion, and the information used to control the placement and operation of the cryoprobe." (column 3, lines 41-45). It is clear that the meaning of this sentence in the context of LePivert's disclosure is as follows: an operator, receiving accurate information about the actual size of eutectic freezing zones, during cryoablation, in real time, can use this *feedback* to modify or correct has ablation activities so as better to achieve his goals. Provision of feedback in the form of graphical representation of a calculation based on real-time collection of physical data does not, however, constitute providing a recommendation. Thus, to take a hypothetical case, an operator, performing cryoablation according to a pre-determined strategy, might discover, on looking at LePivert's display, that several cubic centimeteres of presumably malignant tumor have apparently been left out of the estimated eutectic freezing zone. An operator making this discovery might then decide to extend the freezing time of inserted probes, or to insert an additional probe. The system, in this case, supplies feedback, but not a recommendation. The scene, according to the invention described by claims 16-22, is for an operator to define, using a three-dimensional model of a treatment sitc, an area to be cryoablated and optionally an area to be protected, and for the system, using that initial information, to

recommend use of a particular number of cryoprobes, and perhaps to recommend optimal positioning of those probes. It is submitted that such a response by such a system would constitute a "recommendation" in the accepted meaning of the term, and the LePivert's system, although it provides real-time feedback, is not designed nor does it function to provide recommendations in this sense.

Re claim 4, the Examiner objects that use of a Cartesian coordinate system is obvious over LePivert. Yet it is believed that it is clear from the preceding discussions, that modifying LePivert by including as a design expedient the ability to acquire important (e.g., Cartesian) operational parameters would not, in effect, produce the claimed invention. The Examiner is referred in particular to the discussion of the Examiner's USC § 102 rejections, above.

Therefore it is Applicant's opinion that claims 4 and 16-22 are allowable over LePivert.

Claim Rejections – 35 USC § 103(a) – LePivert in view of Mikus et al.

The Examiner has rejected claims 23, 24, 25, 27-30, and 33 under USC § 103(a) as being unpatentable over LePivert in view of Mikus et al. The Examiner's rejections are respectfully traveresed. It is believed by the Applicant that the explanations and arguments given above with respect to claim 1, with reference to the Examiner's USC § 102 rejections, serve also to overcome these 35 USC § 103(a) rejections.

The Examiner points out in this respect that although LePivret neglects to disclose cryosurgical prostate treatment, Mikus et al. discloses *inter alia*, a cryosurgical prostate treatment and percutaneous prostate cryoablation. The Examiner states that therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. by including as protocol treatment for the prostate. Yet it is believe that it is shown in the various discussions above that such a modification of LePivert's system, to apply that system to treatment of a prostate, would not yield the claimed invention as specified by claims 23, 24, 25, 27-30, and 33, since the result would be a cryoablation system but not a cryoablation planning system, nor would it be a system which could be used for cryoablation planning, as shown above. Therefore it is Applicant's opinion that claims 23, 24, 25, 27-30, and 33 are allowable over LePivert in view of Mikus et al.

Claim Rejections – 35 USC § 103(a) – LePivert in view of Mikus et al. and further in view of Crockett

The Examiner has rejected claim 26 under USC § 103(a) as being unpatentable over LePivert in view of Mikus et al. and further in view of Crockett. The Examiner's rejections are respectfully traveresed. It is believed by the Applicant that the explanations and arguments given above with respect to claim 1, with reference to the Examiner's USC § 102 rejections, serve also to overcome these 35 USC § 103(a) rejections.

The Examiner states in this respect that while LePivert and Mikus neglect to explicitly disclose transperineal cryosurgical prostate treatment, Crocket discloses transperineal cryosurgical prostate treatment. The Examiner states that therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. and further in view of Crockett by including as protocol transperineal treatment for the prostate.

Yet it is believed by the Applicant that it is shown in the various discussions above that such a modification of LePivert's system, to apply that system to treatment of a prostate, would not yield the claimed invention as specified by claim 26, since the result would be a cryoablation system but not a cryoablation planning system, nor would it be a system which could be used for cryoablation planning, as it is shown and discussed above.

Therefore it is Applicants's opinion that claim 26 is allowable over LePivert in view of Mikus et al. and further in view of Crockett.

Claim Rejections – 35 USC § 103(a) – LePivert in view of Mikus et al. and further in view of Fenn et al.

The Examiner has rejected claims 31 and 32 under USC § 103(a) as being unpatentable over LePivert in view of Mikus et al. and further in view of Fenn et al. The Examiner's rejections are respectfully traveresed. It is believed by the Applicant that the explanations and arguments given above with respect to claim 1, with reference to the Examiner's USC § 102 rejections, serve also to overcome these 35 USC § 103(a) rejections.

The Examiner points out in this respect that although LePivret and Mikus neglect to explicitly disclose the use of AUA scores in conjunction with prostate

cryoablation, Fenn et al. does disclose the use of AUA scores in conjunction with prostate cryoablation. The Examiner states that therefore, at the time of the invention it would have been obvious to modify LePivert in view of Mikus et al. and further in view of Fenn et al. by including AUA scores in the protocol.

Yet it is believes that it is clearly shown in the various discussions above that such a modification of LePivert's system would not yield the claimed invention as specified by claims 31 and 32, since the result would be a cryoablation system but not a cryoablation planning system, nor would it be a system which could be used for cryoablation planning, as we have shown above.

Therefore it is Applicant's opinion that claims 31 and 32 are allowable over LePivert in view of Mikus et al. and further in view of Fenn et al.

In view of the above amendments and remarks it is respectfully submitted that claims 1-34 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Sol Sheinbein
Registration No. 25,457

Date: May 18, 2003.

Encl.:
Three months extension fee.